January 7, 2022

EKOS Corporation
Jocelyn Kersten
Director, Regulatory Affairs
22030 20th Avenue SE, Suite 101
Bothell, Washington 98021

Re: K051319
Trade/Device Name: Lysus Infusion System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Jocelyn Kersten:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 15, 2005. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2022.01.07 13:35:45 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2005

EKOS Corporation
c/o Ms. Jocelyn Kersten
Director, Regulatory Affairs
22030 20th Avenue, S.E., Suite 101
Bothell, WA 98021

Re: K051319
Lysus Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: May 18, 2005
Received: May 20, 2005

Dear Ms. Kersten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051319

Device Name: Lysus® Infusion System

Indications For Use: The Lysus® Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051319

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Section 4. 510(k) Summary

General Provisions

Submitter's Name and Address:	EKOS Corporation 22030 20th Ave. SE Suite 101 Bothell, WA 98021
Contact Person:	Jocelyn Kersten 425-482-1108 425-482-1109 (fax) jkersten@EKOSCORP.com
Classification Name:	Catheter, Continuous Flush (KRA)
Common or Usual Name:	Continuous Flush Catheter
Proprietary Name:	Lysus® Infusion System
Name of Predicate Device:	Lysus® Infusion System
510(k) Reference No.:	K042456

Device Description
The system consists of a disposable infusion catheter with removable ultrasound core and an instrument that generates and controls the delivery of energy to the catheter. The infusion catheter contains multiple side holes distributed over the length of the treatment zone. The ultrasound core contains up to 30 ultrasound elements, evenly spaced over the treatment zone. Thermal sensors in the treatment zone monitor transducer temperature.

Intended Use
The Lysus® Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Summary of Technological Characteristics
The software upgrade and revisions to the Instructions for Use described in this notification do not affect the technological characteristics for the Lysus Infusion System.

Test Summary
The software was validated prior to release of the upgraded version.

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Section 5. General Information

Trade and Common Names
Trade Name: Lysus Infusion System
Common Name: Continuous Flush Catheter

Establishment Registration
3001627457

Manufacturing Facility
EKOS Corporation
22030 20th Ave. SE
Suite 101
Bothell, WA 98021

Device Classification
Continuous flush catheters have been classified by the FDA Cardiovascular Panel as Class II (KRA).

Purpose of Notification
The purpose of this SPECIAL 510(k) notification is to seek clearance of a software upgrade and associated revisions to the PT-3 Control Unit Instructions for Use. The software upgrade by itself would not have met the criteria for requiring a new 510(k). However, because revisions to the IFU are also required, this SPECIAL 510(k) is being submitted.

Predicate Device
The Lysus Infusion System is identical in design, composition, function and intended use to the previously cleared Lysus Infusion System (K042456).

Performance Standards
Performance standards have not been promulgated for continuous flush catheters.